



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/516,728	03/01/2000	Thomas O Daniel	1242/12/2	2723

25297 7590 04/22/2003

JENKINS & WILSON, PA
3100 TOWER BLVD
SUITE 1400
DURHAM, NC 27707

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
----------	--------------

1642

DATE MAILED: 04/22/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/516,728

Applicant(s)

DANIEL ET AL.

Examiner

Christopher H Yaen

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-8, 10-14 and 45-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8, 10-14, 45-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 1/6/2003 (paper no 20) is acknowledged and entered into the record. Accordingly, claims 15-44 are canceled.
2. Claims 2-8, 10-1, and 45-55 are pending and examined on the record.

Claim Rejections - 35 USC § 112, 1st paragraph

3. Claims 2-4, 8-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION. Applicant points to page 48 for support, however, there is no specific recitation of the term "selective". The term does not have support within the specification, wherein the specification only specifically discloses "specific" binding of the antibody. Applicant is required to remove the new matter introduced into the claims.

Specification

4. The amendment filed 2/11/2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the substitution of the term "preferentially" with "selectively".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections Withdrawn - 35 USC § 112, 1st paragraph

Art Unit: 1642

5. The rejection of claims 2-4,6-8,10,12-14, and 45-55 under 35 USC 112, 1st paragraph as lacking proper written description as it pertains to fragments or derivatives of the antibody that binds to ECRT/DEP-1 is withdrawn in view of the persuasive arguments presented by the applicant.

Claim Rejections Maintained - 35 USC § 112,2nd paragraph

6. The rejection of claims 2-4, and 8-11 under 35 USC 112, 2nd paragraph is maintained for the reasons of record. Applicant argues that the substitution of the term “preferentially” with “selectively” renders the claim definite. Applicant’s arguments have been carefully considered but are not found persuasive. Applicant’s amendment has not further clarified what the part of the extracellular domain of ECRT/DEP-1 protein the intended antibody is to “selectively” bind to. The ECRT/DEP-1 protein is relatively large and one of skill in the arts would find it difficult to determine the metes and bounds of where within the extracellular domain the antibody is to bind. Furthermore, it is not clear when one of skill would be able to determine when preferential binding would occur.

Claim Rejections Maintained - 35 USC § 102

7. The rejection of claims 2,4,8,14,45, 46 and now newly rejected claims 3,10,45-54 under 35 USC 102(b) is maintained for the reasons of record. Applicant argues that Tonks *et al* (WO 95/30008) do not recite each and every element of the instantly claimed invention, and further argues that the antibody disclosed by Tonks *et al* only teach the generation of antibodies directed to cytoplasmic portions of the DEP-1 protein. Applicant’s arguments have been carefully considered but are not found persuasive. Tonks *et al* clearly discloses more than the antibodies directed to the cytoplasmic

Art Unit: 1642

domains of the DEP-1 protein. For example, page 8 teaches that any antibody (monoclonal, polyclonal, single chain chimeric, antiidiotypic, and CDR grafted antibodies) is useful for the modulating the in vivo activity of the DEP-1 protein. Furthermore, the epitope claimed in the instant invention is drawn to a peptide epitope found in the protein taught by Tonks *et al* (see SEQ ID No: 2), wherein Tonks *et al* clearly claims an antibody that is capable of binding to the extracellular domain of DEP-1 protein. The intended ectodomain claimed in the instant invention is not clearly defined and therefore difficult for one of skill to assess whether the antibody claimed in the instant invention is any different from that claimed by Tonks *et al*. Further still, because there is no direct comparison between the antibody of the instant with that of Tonks *et al*, there is no evidence to suggest that the Tonk's antibody would not bind to the same epitope as that of the instant antibody. And lastly, because Tonks *et al* disclose chimeric antibodies, and because the making of an antibody is well established in the art, humanized antibodies are also anticipated.

Conclusion

8. No claim is allowed.
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the


Art Unit: 1642

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Christopher Yaen
Art Unit 1642
April 21, 2003